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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/781,262	02/18/2004	Geoffrey Smith	BWT-PT001.2	3996

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EXAMINER	
BOESEN, AGNIESZKA	
ART UNIT	PAPER NUMBER
1648	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/24/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/781,262	SMITH ET AL.	
	Examiner	Art Unit	
	Agnieszka Boesen	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) *2-6* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 7-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/21/2004 and 2/18/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Non-Final Office Action is responsive to the communication received October 27, 2006.

Election/Restrictions

Applicant's election without traverse of group I, claim 1 is acknowledged. Claims 2-6 are withdrawn because the claims are drawn to the non-elected invention. Claims 1 and 7-11 are under examination.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on June 21, 2004 and February 18, 2004 are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the Examiner.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 7-11 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in In re Wands, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: 1) scope or breadth of the claims; 2) nature of

the invention; 3) relative level of skill possessed by one of ordinary skill in the art; 4) state of, or the amount of knowledge in, the prior art; 5) level or degree of predictability, or a lack thereof, in the art; 6) amount of guidance or direction provided by the inventor; 7) presence or absence of working examples; and 8) quantity of experimentation required to make and use the claimed invention based upon the content of the supporting disclosure. When the above factors are weighed, it is the Examiner's position that one skilled in the art could not practice the invention without undue experimentation.

The claims are drawn to a medicament for use in treatment and prophylaxis comprising a recombinant poxvirus, which is genetically engineered to be incapable of expressing a native A41L protein. Applicant's disclosure is does not provide sufficient enablement for the claimed medicament.

A medicament can be interpreted to be a drug; a drug by definition is an agent intentioned for the use in the diagnostics, mitigation, treatment, cure, or prevention of disease in humans or in other animals. Pharmaceutical therapies in the absence of *in vivo* clinical data are unpredictable. The specification does not set forth sufficient teachings to allow one skilled in the art to use the claimed medicament for treatment or prophylaxis of infectious diseases. The specification does not provide teachings to establish effective dosages or methods of administration of the claimed recombinant poxvirus treat infections. The specification provides no description or exemplification of how to use the medicament for the prevention, diagnosis, alleviation, treatment, or cure of a disease in the animal to which the substance is administered. Predicting the therapeutic effect of a recombinant viral construct is uncertain and must be tested for each recombinant that may include deletions, insertions or both (see Jackson et al. Journal of

Virology, 2001). The results from experiments in Jackson et al. teach the critical importance of testing a vaccine in order to ensure that it actually performs with the expected result.

No working examples are provided which would provide sufficient guidance to allow one skilled in the art to practice the above embodiments of the invention with a reasonable expectation of success. The specification speculates (see [0087]) that the removal of the A41L gene is likely to increase the immunogenicity and safety of VV strains such as VV MVA, and that the immunogenic VV strain can be used as therapeutic vaccine against various cancers and a range of pathogens, including for instance, malaria, human papilloma virus and human immunodeficiency virus. The specification has shown (see [0056]) that injecting a rabbit subcutaneously with a recombinant A41L deleted VV causes greater infiltration of the surrounding tissue by leukocytes, implying that the deletion makes the virus more visible to the immune system. It is important to note that the VV strain tested is not a rabbit pathogen, therefore the observed effects cannot be extrapolated to the natural host.

The instant specification has not taught how to use the recombinant virus as a medicament for treatment or prophylaxis. The specification provides insufficient guidance, which would allow one of skill in the art to predict the efficacy of the claimed medicament with a reasonable expectation of success. As discussed above undue experimentation would be required to practice the claimed invention commensurate with the scope of the claims. Reasonable correlation must exist between the scope of the claims and scope of enablement set forth. In view of the quantity of experimentation necessary, the limited working examples, the unpredictability of the art, the lack of sufficient guidance in specification, and the breadth of the claims, it would take undue trials and errors to practice the claimed invention.

Claims 1 and 7-11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims are drawn to a medicament comprising a recombinant poxvirus, which is genetically engineered to be incapable of expressing a native A41L protein comprising the amino acid sequence of SEQ ID NO: 2 or a protein having at lest 80% or 95 % amino acid identity with SEQ ID NO: 2.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claim is a partial structure in the form of a recitation of percent identity. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

[Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical

structure of the encompassed genus of polypeptides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

The claims encompass a poxvirus that is incapable of expressing a native A41L protein. The native A41L protein that is not expressed comprises SEQ ID NO: 2. In another embodiment, the pexvirus is incapable of expressing a protein that shares 80% sequence identity with SEQ ID NO: 2. In another embodiment, the poxvirus is incapable of expressing a protein that shares 95% sequence identity with SEQ ID NO: 2.

The claims encompass poxviruses that do not express a large genus of polypeptides. While one of skill can determine whether the poxvirus fails to express SEQ ID NO: 2 (a native A41L protein), one cannot determine whether the poxvirus fails to express variants of SEQ ID NO: 2. The variants of SEQ ID NO: 2 can include any sort of modification (substitution, deletion, insertion), any number of modification, at any point along the sequence set forth in SEQ ID NO: 2. Since Applicant has not provided a representative number of species of poxviruses that fail to express proteins that have less than 100% sequence identity to SEQ ID NO: 2, or a core region of SEQ ID NO: 2 that is retained in the variants such that one would know that a variant A41L protein has not been expressed in the poxvirus, one would not be put in possession of the large genus claimed.

Thus the claims are rejected because it appears that at the time the current invention was made, Applicant was not in possession of various recombinant poxviruses comprising deletion of at least 80% or 95% of A41L protein.

Double Patenting Rejection

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 and 7-11 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3 of U.S. Patent No. 6,355,252 B1.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the current claims and the claims of the U.S. Patent No. 6,355,252 B1 are drawn to a product such as the genetically engineered poxvirus incapable of expressing a native A41L protein. The current claims are generic to all that is recited in the respective claims of the patent, i.e., the patented claims fall entirely within the scope of each of instant claims 1 and 7-11.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Agnieszka Boesen whose telephone number is 571-272-8035. The examiner can normally be reached on 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AB

Agnieszka Boesen, Ph.D.

1/19/2007

Stacy B. Chen 1/22/07

STACY B. CHEN
PRIMARY EXAMINER